

Protherics PLC Annual Report 2002

protherics



## Chief executive officer's review

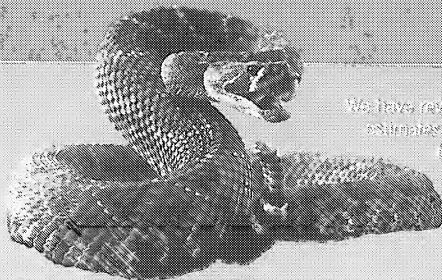
This past year has seen the beginning of a fundamental change in the relationship between the major pharmaceutical companies and their young biotechnology brethren. In recent months 5 of the larger pharmaceutical companies have announced profit warnings, and it is clear that the historic growth rates of 15-20% per annum will be no longer achievable - for many growth may be less than 10% per annum. These lowered growth rates mirror the increasing cost of drug development for big pharma, with lengthening approval times and fewer new drugs coming to market. In contrast, more and more new drugs are being developed by biotechnology companies, typically at lower cost. On average, it costs only half as much for a biotechnology company to reach an FDA approval as big pharma. Furthermore, more targeted biotechnology derived treatments are splintering what used to be simple blockbuster markets into smaller fractions. Five biotechnology derived drugs have achieved sales exceeding \$1 billion. As biotechnology companies become more commercially focused, more of them will seek to market their own products and the number of mid-sized biotechnology companies is likely to grow. As biotechnology derived products reach the market, there is likely to be a shift in the relative capitalisation of biotech vs pharma. This change is already happening, most notably in the US. Nonetheless, we believe biotechnology remains significantly undervalued compared to the established pharma sector.

Protherics is well placed to take advantage of these changing dynamics. Today, in an environment where the balance sheet takes centre stage, we are fortunate to be able to fund our own early stage clinical development. In the US, we have a team with experience from the basics on managing a lot of trials involving 466 patients at more than 100 trial sites. Between October 2000 and December 2001, only 26 drugs were approved by the FDA. Two of these approvals were achieved by Protherics.

With the approval of Digifab™ in the past year, we now have two products marketed in the US. Consequently, we have been able to develop a more commercial perspective. Now, our challenge is to become consistently profitable.

### Operations

This past year has seen larger orders for CroFab™ and Digifab™ than we initially projected. We have worked hard to expand our capabilities in Australia and Wales to meet this demand. In Australia, productivity has improved dramatically in the processing of serum, and last year almost 20 tons of serum were produced. In Wales, our batch sizes of CroFab™ have more than doubled and we have halved the time to completion from 8 to 4 weeks. Further improvements are anticipated in the current year. The appropriate capital expenditure is now being made to increase batch sizes and reduce cost of goods further.



We have revised upwards our  
estimate of the market opportunity  
for CroFab™ to \$75  
million per annum

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## Chief executive officer's review (continued)

Careful attention is being paid to risk management, including dual sourcing of venins, geographical separation of sheep flocks, and filling and freeze-drying.

Looking forward 12 to 18 months, we plan to expand CroFab™ production capacity, allowing us to build adequate inventory and meet the demands of a growing and seasonal market.

As our need for clinical trial quantities of vaccines expands, we find it an advantage to be in direct control of our own FDA and MCA approved manufacturing facility. Manufacturing is often a bottleneck for small companies, who find it difficult to locate a supplier of smaller quantities of drugs for clinical trials. This past year we have successfully transferred the manufacture of our angiotensin vaccine from external contractors. This product is now made at our facility in Wales, at a considerable cost saving.

### Portfolio Review - Marketed products

#### CroFab™

CroFab™ has been very well received by physicians who manage snake envenomations. After a full year in the marketplace, it presents a new standard of care, with an excellent safety profile, even in large doses. Physician demand suggests it will continue to be used earlier, more often, and in milder bites than the previous treatment. We have revised upwards our estimation of the potential size of the market opportunity to \$75 million, as CroFab™ use expands into milder pit viper bites, such as those caused by Copperheads. While the majority of rattlesnake bites occur

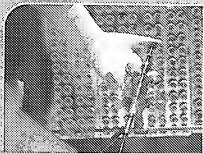
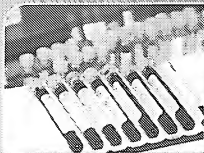
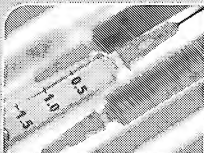
in the Western US, Copperheads are found mostly in the Eastern US. Although seldom fatal, these bites can be serious, with victims often incapacitated for several months. Copperheads account for nearly 40% of pit viper snake bites (including rattlesnakes) in the US. We expect to see a growing number of Copperhead bites treated with CroFab™ as production volumes increase further over the next 12 to 18 months.

#### DigiFab™

DigiFab™ enters a niche market in the US. With only one other competitor in this \$20 million market, we believe that DigiFab™ will make a significant contribution to our revenues in this next financial year. We hope to extend our marketing capability into Canada, where we will market DigiFab™ ourselves, and we are planning an application to the Canadian regulatory authority this year. Bulk sales to Sri Lanka, where the product is used for the management of Oleander poisoning, should provide further modest revenues.

#### ViperaTab®

ViperaTab® has had an excellent year, with sales of approximately £350,000 as hospitals have built inventory in what has been a year with an exceptionally large number of bites. Although ViperaTab® will remain a small product, its contribution is significant as margins are good. A very high penetration has been achieved in the Scandinavian market, and future growth is planned by expansion into other European countries.



## Chief executive officer's review (continued)

### Griffiths (Continued)

This resource, developed for the management of growing change, is focused on MFL Laboratories' (MFL) business, working with V&I, the possibility of using patient data more effectively and addressing the need to make more efficient use of our resources.

### BSE Test

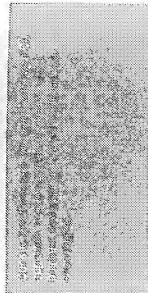
BSE, or "mad cow disease", the infectious agent problem, has been a major issue in human medicine. Our new method for BSE, based on a new test kit, has been used in the United States and Europe. Our new test kit, from our laboratory, Dr. John Schmitt, is currently under evaluation. Griffiths's agreement with Abbott, which allows us to conduct research on BSE, is a significant step in the development of the BSE test kit. We have received our intellectual property rights for the BSE test kit from Abbott. Griffiths's research is in progress.

### Problems Tomorrow

Our activities have and will continue to be focused on developing a growing revenue stream and a future new product. Growing our business, is encouraging. Our staff has been working hard to develop new products and development has been a major focus. Our research and development team has been working hard to develop new products and development has been a major focus. Our research and development team has been working hard to develop new products and development has been a major focus.



Andrew J. Hahn  
Chief Executive Officer



process, we have two critical programs addressing major business issues. First, we are working on the development of a new product, which will be a major step in the development of a new product. Second, we are working on the development of a new product, which will be a major step in the development of a new product.

These projects will be a major step in the development of a new product. We are working on the development of a new product, which will be a major step in the development of a new product. We are working on the development of a new product, which will be a major step in the development of a new product.

At Griffiths, we feel we must do things differently and we must do things differently. We are working on the development of a new product, which will be a major step in the development of a new product. We are working on the development of a new product, which will be a major step in the development of a new product.

Andrew J. Hahn



Griffiths is a leading provider of research and development services to the pharmaceutical industry. We are working on the development of a new product, which will be a major step in the development of a new product. We are working on the development of a new product, which will be a major step in the development of a new product.